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16. Abstracts: This report is a status report and action guide which reflects the Agency's commitment to the Subcommittee on Administrative Practice and Procedure of the Committee on the Judiciary , regarding ~~xxxxxxxxxx~~ the depth of data review undertaken by the Agency prior to reregistration. While it did not start out ~~xx~~ to be written for ~~xxxx~~ that purpose, two events occurred to turn it in that direction: criticism from that Committee ~~xxxxxxxxx~~ concerning the EPA's depth of data review and a preliminary injunction issued by the U.S. District Court to require the EPA to consider basic modifications to its reregistration data requirements.

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NOTE TO THE READER:

The attached document was intended for distribution for December 1976. Late in that month, two developments occurred which may prove to impact on program operations in ways not foreseen when the paper was originally prepared. First, the Senate Subcommittee on Administrative Practice and Procedure of the Committee on the Judiciary issued a draft report critical of the depth of data review undertaken by the Agency prior to reregistration. The report now before you has been rewritten since its previous draft to reflect the Agency's commitment to the Senate committee regarding data review. Secondly, a preliminary injunction recently issued by a United States District Court has required the Agency to consider basic modifications to its reregistration data requirements.

The Agency is now reviewing resources, adjusting program plans, and preparing to go before Congress for the FIFRA reauthorization hearings with these new developments in mind. The public will be kept informed throughout the next few months as events unfold through prepared statements, reports, and Federal Register notices.

Since a new Administrator will soon assume leadership of the Agency, this document may be a logical starting point to discussion of the operation of Pesticide Programs in the future. We would, therefore, welcome your comments and suggestions.

Although this is a draft document and the new Administrator has not had an opportunity to review it, the Office of Pesticide Programs intends to begin implementing the policy decisions and changes discussed herein except in those instances where they may conflict with existing formal policy statements or legal constraints.

PESTICIDE PROGRAMS
A STATUS REPORT AND GUIDE FOR ACTION
DECEMBER 1976

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PESTICIDE PROGRAMS
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I. BACKGROUND

A. Purpose. The deadline for full implementation of the 1972 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was originally set for October 1976, later extended until October 1977. Since the deadline is approximately one year away, this is an appropriate time to review what has been accomplished and what remains to be done. Significant progress has been made, but frustrating delays have also occurred. There is some confusion about just where we stand in implementing the Act, particularly in the effort to reregister and classify all the pesticides presently marketed in this country.

These have been active and controversial years. Although it may appear that progress has been tortuously slow, much forward movement has been made, despite unforeseen delays due to lengthy public debate on rulemaking, an in-depth Congressional oversight period during which the future of some major program elements were uncertain, and some unexpected discoveries affecting our fundamental assumptions for reregistration purposes.

Pesticide regulation affects many interests: the Congress, the regulated industry, farm groups, professional applicators, other pesticide users, our State and Federal colleagues, environmental groups, consumer groups, academia, and the general public. All these groups are the audience for this paper and we thus include basic background for those less familiar with the Agency's development of pesticide regulatory policy, while also providing specific discussions of problem areas and solutions. This paper is intended to provide a description of our goals, an historical perspective of pesticide regulation, a status report on some of the major areas of difficulty, and our proposed solutions to the problems.

We cannot provide all the answers now. Where we cannot, we can nevertheless propose pathways to decisions. We need your constructive thoughts on these issues. The challenges posed by this transition time between the "old" and "new" FIFRA must be met with patience and careful thought, and above all with a cooperative spirit between the regulators, the regulated, and the many interests affected by EPA's decision making.

This document is not a replacement for the long-range Pesticides Strategy paper. The Strategy, now being developed, will address in detail the Agency's objectives and plans for the entire regulatory program through 1981. This paper addresses immediate concerns and issues. It is a discussion of short-term problems (although some of the solutions may be extended over a period of time) to deal with the major current dilemmas which need prompt attention.

B. Program Objectives. The primary mandate of the Office of Pesticide Programs is to protect human health and the environment from unreasonable adverse effects of pesticide use. Pesticides are deliberately introduced into the environment to achieve a distinct benefit. Decisions on pesticides must thus consider not only the possible adverse effects from pesticide use, but also the potential effects on food production and health of the absence of these pest control tools. It would not serve this nation to restrict the use of pesticides to the point that an adequate supply of food and fiber could not be produced or protected, or that disease vectors or structural pests could not be adequately controlled. Nor would it be a service to permit the continued use of pesticides to the detriment of the health of our citizens. The heart of the regulatory objective, then, is to assess and determine the acceptability of risks as balanced against the benefits.

Social policy in this context requires that the benefits, or social utility, afforded by a pesticide be weighed against its undesirable consequences. The standard guiding all pesticide regulatory decisions is "unreasonable adverse effects on the environment." This is defined by law as "... any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." Risk/benefit decision-making is not easy; there are no magic formulas for achieving the absolutely right answer. Neither side of the equation is known with certainty, since each involves some non-quantifiable inputs. The key question is simply, "What is an acceptable level of risk?" That determination is not based on science, economics, or social factors alone; all components and their interrelationships must be considered in the regulatory decision-making process. It is, in short, decision-making which most typically involves extrapolation beyond the strict bounds of scientific measurement: the very subjective area of trans-science.

Thus, in fulfilling our objective to protect the public from unreasonable adverse effects of pesticide use, we turn to three crucial elements: 1) obtaining the most up-to-date, complete, and accurate information available, 2) conducting a thorough assessment of risks and benefits and 3) making decisions in the open, with as much public participation as possible.

C. Historical Perspective. EPA assumed pesticide regulation responsibilities from the Department of Agriculture and the Federal Food and Drug Administration in 1970. All pesticides Federally registered before 1972 were subject to the 1947 FIFRA, an Act passed when the great benefits of pesticide use were first being recognized. It took many years to realize that some of these products, although efficient in pest control, could cause subtle long term adverse effects in man, wildlife, and the environment. In addition, overuse of certain chemicals was creating a resistance in some pests.

Congress responded to the need for a more comprehensive regulatory scheme with the passage of the Federal Environmental Pesticide Control Act to amend FIFRA in 1972. The amendments transformed FIFRA from a labeling Act to a comprehensive regulatory Act, affecting all aspects of pesticide use. EPA assumed responsibility for regulating pesticides from the early experimental stages, through premarket data review, to use in the environment. The Agency was assigned responsibility to monitor for long term effects and to respond to accumulated scientific knowledge. And we were to get underway with two giant tasks: the registration, reregistration, and classification of all pesticides marketed in the country; and the establishment with the States of programs to train and certify applicators who would need to use restricted pesticide products.

Several important factors were at work at the time the 1972 amended FIFRA was passed. They are still of critical importance:

- Rapidly advancing scientific knowledge and public interest which escalates the serious question of long-term effects -- cancer, mutagenesis, birth defects, and nervous system, blood and organ dysfunctions.

- Advancing monitoring technology that increased our ability to detect pesticides first in parts per million, then parts per billion, and now parts per trillion, beyond our ability to estimate significance;

- o The results of monitoring studies using such technology showing that pesticide residues are found in soil, water, air, and can accumulate in wildlife and man;

- o Increasingly complicated legal issues that are slow and costly to resolve;

- o Increasingly complicated economic and political factors that must be considered.

The Congress further amended the FIFRA in 1975 after a lengthy oversight process. The latest amendments are intended to ensure that all agricultural and scientific ramifications of proposed rulemaking or cancellation actions are explored. They require EPA to submit copies of proposed regulations or notices of intent to cancel to the Secretary of USDA and to a Scientific Advisory Panel 60 days before public notification. Final notices and rulemaking are to be submitted 30 days prior to public notification. EPA must also submit to USDA an assessment of the agricultural impact of proposed cancellation actions. The Senate and House Agricultural Committees are also informed in advance of our significant actions.

D. Accomplishments. Despite the complexities, progress has been slow but steady. Regulations began appearing in 1973 and most major rulemaking followed over the subsequent three years:

July 1973: Section 6, Administrative Review (cancellation and suspension procedures);

November 1973: Section 7, Registration of Establishments;

December 1973: Section 18, Emergency Exemptions;

May 1974: Section 19, Disposal and Storage;

May 1974: Farm Worker Protection Standards;

July 1974: Section 14(a), Assessment of Civil Penalties;

September 1974: Section 8, Books and Records;

October 1974: Section 4, Standards for Certification of Applicators;

March 1975: Section 4, State Plans for Certification of Applicators;

March 1975: Subpart D, Section 6, Reconsideration of Previous Cancellation Decisions;

April 1975: Section 5, Experimental Use Permits;

June 1975: Proposed Registration Guidelines;

May 1975: Section 17, Notice to Foreign Governments;

July 1975: Section 3, Registration, Reregistration, and Classification; and

September 1975: Proposed 24(c), Special Local Needs.

In addition, some significant policy statements have been issued under the new Act: two papers on the compensation for data provisions of the Act, Section 3(c)(1)(D) (November 1973 and January 1976); the categorization and call-in scheme for reregistration (February 1976); the procedures for handling problem chemicals through the Office of Special Pesticide Review (December 1975); the procedures for handling new registrations identical or substantially similar to already registered products (May 1976); and five Pesticide Enforcement Policy Statements regarding how the Agency will enforce "use inconsistent with the label" under Section 12(a)(2)(G):

#1, less than label dosage -- May 1975,

#2, unnamed structural pests -- September 1975,

#3, State registered products -- April 1976,

#4, preventive treatments -- July 1976, and

#5, unnamed agricultural pests -- September 1976.

#6, use and labeling of service containers -- December 1976.

Twenty-nine Pesticide Regulation (PR) notices have been issued to registrants on a variety of policy issues. In addition, the Agency proposed an EPA-wide policy on addressing chemical carcinogens, including potential pesticide carcinogens, in May of 1976.

During this time, too, we have been processing the applications which come in daily. In the past 4 years, we have issued more than 145,000 supplemental registrations; 16,930 amended registrations, and 11,140 new registrations. More than 500 experimental permits, and more than 110 emergency exemptions have been processed. In addition, great progress has been made by joint effort with USDA Extension Service (ES), EPA Regions, and the States in starting applicator certification. As of this writing, 47 State Plans have been submitted for approval, and more than 225,000 applicators have gone through training programs.

E. Problems. Although we are pleased with these accomplishments, major program decisions must be made to complete the task of implementing FIFRA. Many of our problems are caused by the dynamics of the transition from the old law to the new law. Registrants knew where they stood under the old Act. They know where they will stand when the 1972 FIFRA is implemented. But they are confused and impatient about their status during this important in-between period. Industry, users, and environmentalists alike are equally concerned as we try to sort out an avalanche of complex and new variables.

To explain our policies and problems, this paper will systematically address two of the primary functions of the Office of Pesticide Programs in achieving program objectives: premarket review of pesticide products, and use regulations.

Part II will describe the foundation of the regulatory process and will discuss data requirements, the status of the data, the problems concerning the data, ways to convey requirements to registrants and the public, registration and reregistration procedures, and the problems being experienced during the transition between the old and new Acts. Part III will discuss the use aspects of the regulatory process, specifically applicator certification and training. Part IV will discuss the Office of Pesticide Programs staffing and organization to carry out program functions.

II. PREMARKET REVIEW

A. Background. Before a pesticide can be registered by EPA, the applicant must demonstrate to the Agency that the product will perform as claimed on the label, and that its use will not cause unreasonable adverse effects on man or the environment. A registration application, then, must be supported by data on efficacy, human safety, chemistry, fish and wildlife, and environmental effects.

We are presently engaged in two simultaneous processes under the new statute:

- registering pesticides not previously on the market, and
- reregistering those products already registered under the 1947 Act.

A system to reregister the more than 35,000 products which are already Federally registered was developed in 1973. Products will be grouped into "batches"; all products in a batch will be "called in" for reregistration according to chemical similarities in their active ingredients.

In taking this approach, the Agency is attempting to minimize potential confusion during the reregistration process, and to facilitate the submission of reregistration applications by clarifying what information is or will be expected for the applicant to achieve full registration. The entire onus for submitting a full and complete application with supporting data could have been placed squarely on the industry. The Agency chose the task sharing approach, however, which we believed would be the most equitable and orderly option.

Applications will be called in through the Guidance Package, a document which:

- informs the registrant of the proposed classification of his product (either general or restricted use),
- cites pertinent data already on file,
- provides label information, and
- specifies any additional data requirements to be filled.

When long-term data must be accumulated, presuming there are no data indicating adverse effects in our files, the registrant will receive a conditional registration for the specified period of time necessary to conduct the additional tests.

The primary purposes of reregistration are to:

- classify products,
- update labeling,
- identify and fill data gaps, and
- review data on hand to ensure that the problem pesticides will be identified and subjected to in-depth scrutiny.

The in-depth risk/benefit review procedure is triggered when the risk criteria enumerated in the Section 3 regulations are met or exceeded. The Agency then "presumes" that a reregistration will not be issued. The registrant, users and the public may "rebut" this presumption by submitting information showing that there is no risk, that the hazard can be reduced by special use directions, packaging, or other means, or that the benefits of the pesticide's use outweigh the risks.

This information-gathering and decision-making process, which will be discussed in greater detail later, is known as "rebuttable presumption against registration" (RPAR).

B. Priorities. The Agency has set registration/ reregistration priorities to provide the greatest public protection and best use of limited resources:

1. Classification and reregistration of those product uses most likely to be restricted.

2. Basic registration/cancellation decisions on those products triggering presumptions against registration on the basis of potential adverse health effects.

3. Making the basic registration process more workable by such efforts as improving data cataloging, data validation and regional support to help firms properly make application.

4. Reregistration of products destined for general use.

While we will not meet the statutory deadline of October 1977, devoting top resources to classification of restricted uses, reviewing pesticides which potentially cause unreasonable adverse effects, and smoothing the registration mechanisms, will be responsive to essential goals of the statute. An important point to note is that products will remain on the market regardless of the October 1977 date until action on reregistration is taken.

C. Data Requirements:

1. Background. There are three places where data requirements are articulated:

The Law: The statute requires under Section 3(c)(5) that the Administrator make a finding prior to registration that a product, among other things, will perform its intended function without unreasonable adverse effects on the environment. To make this finding the Act authorizes the Administrator to request test data in support of the application for registration.

The Regulations: To write regulations implementing that standard has been one of the biggest challenges before the Office of Pesticide Programs. Efforts to include the public in the decision making process for devising the registration, reregistration, and classification regulations were unprecedented. In July of 1974, a public meeting was held in Washington in which the first draft of the regulations -- which had previously been mailed to over 200 interested parties -- was openly discussed. That meeting was followed by the formally proposed regulations in October of that year. Because of the tremendous impact these regulations were to have, and the intense public interest, there was an extensive comment period on the proposals. Final regulations were not issued until July 1975, and were effective in August.

The regulations enumerate the basic registration requirements (§162.8) and establish criteria for identifying those products with potential for an "unreasonable adverse effect" (§162.11). The regulations reflect the Agency's concern about the potential chronic effects of pesticides on human health. They include requirements for oncogenic, mutagenic, teratogenic, and reproductive testing where appropriate to adequately assess health effects in addition to environmental chemistry, wildlife, phototoxicity, chemistry, and efficacy data.

The Guidelines: To more clearly define specific data requirements to support registration, Section 3(c)(2) of the Act instructs the Agency to issue Guidelines. The Guidelines will specify, among other things:

.data requirements for registration,
.characteristics of acceptable testing,
.examples of acceptable test methods, and
.the information required in test reports.

Proposed Guidelines were published in the Federal Register on June 25, 1975. The Agency is revising this document after careful review of the large number of comments received.

The Guidelines represent a difficult concept: the regulatory articulation of scientific requirements. In science, practically nothing is absolute. In regulatory affairs, clear-cut answers are required. In science, the search for knowledge never ends. In regulatory affairs, decisions must be made on the basis of the knowledge available. In science, the freedom to experiment and innovate is cherished. In regulatory affairs, a definitive method of measuring and judging must be established.

Competent regulatory decisions must, of course, be made largely on the basis of scientific information. EPA, therefore, must find a way to reconcile these differences. In the final Registration Guidelines, EPA will provide minimum standards for acceptable testing. Thus, with respect to many types of toxicity testing, the Registration Guidelines will not only indicate when the testing is required, but also specify such factors as reliability, preferred species of test animals and routes of administration, numbers of dose levels to be tested, reporting requirements and so on. In practically all instances, these specifications have been derived from, or are consistent with, test protocols already published in the scientific literature.

2. Data Requirements: PROBLEMS

PROBLEM #1: Should the Section 3 regulations be modified?

Discussion. The State-Federal FIFRA Implementation Advisory Committee (SFFIAC) has suggested several changes in the registration/reregistration/classification regulations. SFFIAC's major recommendations are to:

- .better define "use inconsistent with the label,"
- .increase flexibility in efficacy and hazard data requirements,
- .re-establish negligible residue concept,
- .clarify precautionary statement requirements, and
- .increase flexibility of the numerical toxicity indicators used to trigger an in-depth risk/benefit review or classify products.

Agency commitment. Amendments to the Section 3 regulations will be prepared for transmittal to USDA, Congress, and the Scientific Advisory Panel in early 1977 as the Agency deems appropriate.

PROBLEM #2: Will EPA insist that new testing conform -- without exception -- to the minimum standards specified in the Guidelines?

Discussion. Testing that meets the standards in all respects may not always be accepted without question, but testing that does not meet the standards is much more likely to run into problems.

When a prospective registration applicant believes that a particular testing standard is inapplicable or impractical in a particular case, or when the applicant wishes to deviate from the standards in any significant respect, consultation with EPA before testing begins will be strongly advised. Alternatively, the applicant can proceed with testing and take a chance that it may be accepted. In either case, it will be up to the applicant to spell out reasons why non-conforming tests should be accepted. Such reasoning will have to include a persuasive argument showing that the non-conforming testing will not (or did not) significantly reduce the likelihood of discovering any adverse effects that a pesticide may be capable of producing. In short, insofar as new testing is concerned, applicants will have to take the initiative in persuading EPA to accept testing that will not (or did not) meet the minimum standards.

Agency commitment. Taking into account the intricacies of toxicological testing and the diversity of scientific opinion on many aspects of such testing, EPA's position must be that while the minimum standards are designed to facilitate decision-making, testing that does not conform in all respects does not necessarily preclude decision-making. To the extent that EPA's scientists can reach reasoned conclusions from test results (even though the tests fell somewhat short of EPA's standards) without making extrapolations or assumptions that have no foundation in the test results or in other pertinent data, such test results will not be rejected. In such cases, of course, the EPA scientists performing the evaluation will thoroughly document their reasoning so that the public may be fully informed.

PROBLEM #3: How will the Registration Guidelines be applied to data submitted in years past?

Discussion. Thousands of tests performed over the past 25 years will be examined during reregistration. Many of them, however, do not satisfy the specific criteria of new testing standards in many respects. EPA could, of course, reject all such nonconforming tests. The testing standards set forth in the Registration Guidelines, however, are not an absolute prerequisite for decision-making. For instance, the results of a test performed with only 40 animals per dose level, when considered in light of both the remainder of the test protocol and other available information about the pesticide, may very well enable a scientist to reach sound conclusions regarding the pesticide's chronic toxicity.

Agency commitment. In the reregistration process, EPA will necessarily take the initiative in evaluating nonconforming testing. EPA will determine whether tests performed before the issuance of the Registration Guidelines -- if they do not meet the new minimum standards -- can be considered scientifically valid and provide the information needed for decision-making. Again, the EPA scientists who make such judgments will document their reasoning.

The key issue to consider in reviewing non-conforming tests is validity -- can the Agency have confidence in the results? In each case, EPA must assess the information present and determine if 1) the data are reliable and meet or exceed the "unreasonable adverse effects" criteria enumerated in the Section 3 regulations, and thus that an RPAR is triggered, 2) the data are reliable and show a negative effect, thus supporting registration or reregistration, or 3) the test was so poorly conducted that the results are meaningless, and thus that a data gap exists.

PROBLEM #4 How can the Agency successfully convey data requirements?

Discussion. It is not a simple matter to convey a complex set of data requirements to an applicant or any other interested party for the first time. But it is important to do so. It wastes company resources to submit and resubmit incomplete applications for registration. This is most important to the small manufacturer or formulator and to potential minor use registrants. And it wastes Agency resources to deal with procedural matters, when there are so many substantive issues which demand attention.

After the Section 3 regulations were published last year, the Agency sent a team across the nation to explain the new requirements and to assist registrants in understanding and preparing for reregistration. Nine workshops in 10 cities were attended by approximately 2000 registrants. The Agency found that it is very helpful to discuss requirements face to face with registrants, and we should thus not only be able to express data requirements in written form, but also be available for personal explanations. Because of the changes in the registration process since those workshops, further personal guidance should be available to registrants at the local level.

Agency commitment. To convey data requirements, the Agency will:

. issue the Guidelines. The schedule is as follows:

-- Hazard Evaluation and Chemistry Sections: first quarter 1977: through internal EPA review groups; second quarter 1977: to USDA, Congress, and the Scientific Advisory Panel; third quarter 1977: publish in Federal Register. A document with which the EPA staff can work will be complete by the first of March and will be available to registrants and the public and will be used while the Guidelines are under review by the rest of the Agency. Notice of availability will be published in the Federal Register after EPA working group approval, but before interagency review.

. train Regional personnel to assist registrants at the local level. The initial phase of this training program is near completion, and additional programs and instructions will follow.

. invite registrants to use the Regional expertise. PR Notice 76-2 was issued on June 21, 1976, notifying all manufacturers and formulators of the availability of Regional assistance.

D. Data Availability, Validity, and Applicability

1. Background

a) Company data files.

What data do we have, and how good is it? The data required by the Agency is received from individual manufacturers in support of product registrations. Most of the data on hand, therefore, is in data files submitted by companies. When the 1972 Act was passed, none of the data was cataloged. It was in different formats, and reflected the various regulatory standards acceptable at the time of submission. Data files thus go back many years and range widely in terms of quantity, quality, and organization.

Under the old FIFRA, products could be registered in accordance with "accepted patterns of use." In other words, a reviewer could issue a registration based on the fact that a similar product was already registered. An application did not have to be linked to specific data. Now, in accordance with Section 3 of the amended Act, the Agency must be able to identify specific data in support of any registered product. This does not mean that reams of duplicate data must be submitted nor that duplicate testing would be required; it does mean, however, that specific data references must be associated with each registration.

b) Data Validation.

This is an area of particular concern to the Agency. To discuss it properly, we must first establish the historical perspective for data examination for the reregistration process. In 1973, during the planning stages for the new registration/reregistration program, we were operating on the basis of certain important precepts and constraints:

- first, there would be no significant increase in resources, particularly manpower;
- there was a Congressional deadline to reregister some 35,000 Federally registered products and register for the first time an estimated 15,000 intrastate products by October 1976, now, of course, by October 1977;
- the Agency had to maintain a reasonable response capability to continue handling applications for new registration, tolerance, and experimental use permits;
- the Agency anticipated that data gaps would exist because of new data requirements. However, we made three very important assumptions about the data already on file;
  - -- data results were derived from testing which generally was properly performed and fully reported;
  - -- they were initially reviewed in accordance with scientific standards appropriate for today's decision-making; and
  - -- data problems were generally identified by prior reviewers and followed up in terms of resolving questions or obtaining additional studies as needed.

It was recognized that these assumptions would not hold for every case. However, it was anticipated that in those few instances when imperfect decisions had been drawn, the potential errors would appear when registrations had to be renewed (the law requires renewal every 5 years) and could be addressed then. All in all, we believed that our suppositions were sound, and our resources could be focused on the obvious problem products, label improvements, and the collection of additional data where gaps were discovered.

Our assumptions, as will be discussed in the problem section below, did not prove to be viable. Increased emphasis has been placed on validation during the past year. Data validation will consist of three primary elements in the regulatory context:

1. First, the data must be evaluated on a purely scientific basis to establish the scientific soundness of the conclusions.

2. If these studies are found to be scientifically sound, their applicability to the regulatory decision must be determined, after consideration of other supplementary data and the Guidelines.

3. Finally, validation consists of a statement of the scientific decision on the adequacy of the data to fulfill the standard and a summation of the basis for the decision.

One difficult concept relates to the absence of data as related to the presence of risk. Bad data or missing data, unless falsified to show opposite conclusions, does not equal a potential human or environmental risk. The presence or absence of a certain type of study reduces the certainty of making a proper finding of unreasonable adverse effect but does nevertheless not show a risk to be present. Data validity shows hopefully first, that studies are not fraudulently conceived or reported; second, that they are relevant or not; and, third, identifies where data gaps exist which must be filled in order to reduce the potential for a regulatory misjudgment.

c) Data Accessibility.

Company data files are accessible to the public and the industry to varying degrees. Section 3(c)(2) provides that the Administrator of EPA "shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision." However, the Agency is specifically prohibited in Section 10 from releasing "trade secrets or commercial or financial information" pertaining to registration applications.

Congress in deliberating on the 1972 FIFRA amendments grappled with the issue of whether companies who do not develop their own data should get a "free ride" by relying on data already submitted by another registrant. To equalize the costs of data development, a Section was incorporated into FIFRA which prohibits the Administrator from considering data submitted by one applicant in support of another application unless the originator of the data has given permission or the applicant has offered to pay reasonable compensation for use of the data. That is, of course Section 3(c)(1)(D). In part, this Section became effective with the issuance in the Federal Register of the Interim Policy Statement (IPS) of November 1973. According to the IPS, data first submitted on or after October 21, 1972, were eligible for compensation under 3(c)(1)(D). This policy pertained to all applications for registration submitted after November 19, 1973. However, in 1975 Congress further amended the FIFRA to specify that data submitted on or after January 1, 1970, were eligible for compensation and that the compensation provisions applied to all applications for registration submitted on or after October 21, 1972, and not approved before November 28, 1975, the effective date of the amendment.

The issue is further complicated because various segments of the pesticide industry are disagreeing as to what data are covered by Section 10, Trade Secrets. Data covered by Section 10 cannot be relied upon by the Administrator or released to the public without consent of the owner. In addition, small formulators are concerned about signing an offer to pay statement, or "blank check," which commits them to paying an unspecified sum in the future. Congress is concerned that the data compensation provisions may be encouraging a monopoly within the industry to the detriment of the small businessman. Many of these issues are now being considered in the courts, which will ultimately resolve some of the fundamental problems.

We have issued a second Federal Register notice (January 1976) stating our current policy with regard to data compensation and describing the changes to this Section brought about by the 1975 amendment. This amendment further provided that registration not be delayed pending the determination of reasonable compensation in the courts.

It has been EPA's position that the Agency should proceed with registration if an applicant either has permission to use data submitted by a previous registrant or has signed an offer to pay reasonable compensation for the use of the data, unless the Agency is specifically prohibited from utilizing the supporting data by court order.

2. Data Availability, Validity, and Applicability: PROBLEMS

PROBLEM #1: How and when will the Agency organize the data on file in suppport of registrations?

Discussion. As stated in the background section, company data have never been completely sorted or organized. This creates a problem for the industry in referencing data to support registrations and for the Agency in locating specific files.

Agency Commitment. EPA is now in the progess of cataloging all company data in the files.

The first step was to index the volumes of data currently in our data library. We have now identified 50,000 volumes of company data, i.e., we have an index of the physical description of each volume on hand.

The second major step in the cataloging process will be to identify the tests within each volume (each volume averages 20-22 tests). An OPP contractor is cataloging these tests at a steadily increasing rate. We have twice accelerated the contractor's schedule to obtain maximum speed: for the priority chemicals (those which may be subject to RPAR and the restricted classification), the job will be complete in January of 1977, the entire file to be completed by April 1977.

PROBLEM #2: Are data in EPA files reliable and properly reported?

Discussion. Based on the precepts developed when the new registration, reregistration, and classification regulations were written (see page 14), the Agency began sorting pesticides into three categories in 1974/75: those for which the rebuttable presumption against registration would likely be triggered; those potentially restricted to use by certified applicators; and those for general use candidacy. In looking into past files, the Agency sought what was missing, i.e., what now-required studies had not been completed, rather than what was on hand. Our primary purpose was to identify data gaps which could then be filled during the rerergistration process.

Then in 1976, new information came to light which questioned the assumptions of the registration and reregistration process. In January, it was disclosed in discussion with FDA and GAO officials and during Senate hearings that some toxicological data provided to FDA were of questionable reliability. An independent toxicologist was contracted to look into a sample of pesticide data. Based on his preliminary findings, the Office of Pesticide Programs established its own review force. In April 1976 we developed, in cooperation with FDA, a thorough auditing program to examine laboratory data validity. Serious questions were raised about the adequacy of the testing in EPA files, and the completeness of the Agency's own review and followup.

As a result of these efforts, we now know that it is not enough to determine whether a study is present. Preregistration review must go beyond that to determine what the study showed and whether proper follow-up was taken. Grossly inadequate and misreported previous testing will hopefully not be widespread; however, the problem cases already identified require us to go to the extra effort.

Agency Commitment. To resolve the reliability of data question, several important steps are to be taken:

First -- the Agency is initiating an auditing program in conjunction with FDA to determine if:

1. The testing in audited files was performed in accordance with the test protocol selected by the sponsor (i.e., pesticide company) or testing laboratory.

2. Any errors were made that may have materially affected the test results.

3. Any practices were followed that may have biased the test results or obscured the biological effect of the chemical.

4. Test procedures or results or any relevant data were materially altered during or after testing.

5. Test reports submitted to EPA (or predecessor agencies) fully and accurately reflected all material facts regarding the actual test procedures and results.

Second -- EPA published an advance notice of proposed rules on October 5, 1976, which would require toxicology test reports to include certain information to provide the Agency with a greater degree of confidence that the work has been properly conducted. Public comment has been solicited.

PROBLEM: #3: How deeply should data in EPA files be reviewed prior to reregistration?

Discussion: Just what "review of data" means has recently become a matter of some considerable concern. A Senate subcommittee report has stated that the Agency has misled the public as to the depth of review of data on file prior to reregistration. Obviously, there are several levels of data review -- each with specific implications regarding resources, timeliness, and public impact -- which are possible. The following logical review stages could be applied:

1) identify all the acute, subacute, and chronic toxicity data on hazard to humans, domestic animals, fish and wildlife and all environmental chemistry data currently in our files;

2) review any existing Agency summary and analyses of these data;

3) review summaries of use history, if any, including any accident reports;

4) review the full test report which was submitted by the applicant and validate the data in accordance with present day standards. The test report is the narrative and graphic description of the test method and results;

5) compile and review any articles and monographs readily available in the open literature and any Agency working documents which bear on the effects of the compound;

6) review the raw data and slides which were the bases for the test report which was submitted to the Agency. Raw data includes the laboratory workbooks and any other recorded material;

7) perform an extensive literature search and review any articles which bear on the effects of the compound.

When the Agency planned its original strategy for reregistration in 1973, it was decided that the best utilization of public resources in the alloted time would be to basically divide pesticides into two primary categories: suspected problems and those which the use history and the literature implied were not posing unreasonable adverse effects. Those suspected problem pesticides (those which had greatest potential for causing an unreasonable adverse effect)

would undergo a thorough data validation and risk/benefit review through the RPAR process. The other pesticides would be classified, their labeling upgraded, and data gaps identified and new testing required in accordance with the regulations implementing Section 3 of the amended Act. Our approach, then, was to screen out the "bad actors" to which our resources could be immediately devoted while further testing was being conducted on the other pesticides which could be more thoroughly reviewed after the new test results were received.

However, due to the discoveries made earlier in the year as discussed above regarding data on hand, our original approach was not affording adequate examination of data in our files for non-RPAR products.

A full review, including examination of every piece of paper in each file, data validation including recourse to tissue slides and raw data where needed, literature search and outside consultation on risk data as well as an assessment of economic and social importance of the compound's uses, alternatives, and use history would at best require about two man-years of effort per chemical. A basic de novo review of all the data on hand, then, could take between 10 - 20 years to accomplish at our current resource level, especially considering the scarcity of hazard evaluation scientists. At the other extreme, we could simply look at the first level of review and give primary priority to identifying data gaps. That kind of job could be accomplished in one or two years even with current resources. And in between those two options are various levels of review depth and resource commitments which could affect the thoroughness and timeliness of the task.

The more in-depth the data review prior to reregistration, the greater is the eventual certainty that the public will not be exposed to an unreasonable adverse effect based on all available knowledge. But on the other hand, the longer the Agency spends on reviewing data on hand, the longer it will be until Guidance Packages identifying data gaps and requiring additional testing are issued, and thus the longer it will be until the review of each product takes place. In actuality, there is no alternative but to sacrifice some degree of either certainty or timeliness. The policy question is then: is the public best protected by a thorough in-house review of those data in our files which delays filling data gaps, or is the public interest best served by a screening process which seeks to identify the "bad actors" and -- while these compounds are going through the RPAR process -- increase the data base from which a more complete assessment can be made? Clearly, this question comes down to how the public will be best protected.

Agency Commitment. The Agency will conduct a review on bioeffects and environmental chemistry data through level five as explained above. As far as efficacy data are concerned, we are considering relying on a certification either by the applicant or USDA that the pesticide will perform per label claims, provided that any new use will require efficacy data, and all efficacy data on disinfectants or other products related to public health will be reviewed and validated. General chemistry data will be required with each application.

The general reregistration strategy will remain the same, that is, products will be called in by batches and Guidance Packages will be issued. However, the internal review before the development of the Guidance Package will be substantially amended. The Agency will:

1. look at the files through level 5, and determine whether studies are valid and proper follow-up on reviewers' questions has occurred in the past;

2. develop standard procedure for our own reviewers to use in documenting their findings, so that the basis for the decision is clear;

3. consult with other Agencies in addition to looking to primary literature sources;

4. present all pertinent findings to an internal review panel before the issuance of the Specific Guidance Package to assure scientific, legal, and policy consistency and credibility.

The heart of the new procedures will be a chemical review file (CRF). The CRF will contain a summation of all supporting data, the use history of the pesticide, literature citations, and all other pertinent information. The review panel will examine the CRF for content and completeness, concur in the classification conclusions, the RPAR conclusions, and the action recommendations.

PROBLEM #4: What data are eligible for compensation, and can the Agency register in cases where a compensation dispute is outstanding?

Discussion. While 3(c)(1)(D) now provides clear direction as to what data are compensable, if used by another registrant in support of a subsequent registration, it is not certain what data are available

for use in this way. The trade secret provisions of Section 10 of the Act significantly affect the availability of data. Specifically, test data submitted before January 1970 may be relied on without consent of the owner firm, without an offer to pay compensation, and without regard to Section 10. (This does not mean such data may be released, but rather may be considered internally for purposes of reviewing registration applications). However, the right to rely on test data submitted on or after January 1, 1970, depends upon the applicability of Section 10. If the data are not confidential, the data may be relied upon by other applicants with or without the consent of the owner (although in this case the applicant must offer to pay reasonable compensation). If the data are confidential they may be relied upon only with the consent of the owner so long as the provisions of 3(c)(1)(D) are observed. There is thus a reciprocal relationship between 3(c)(1)(D) and Section 10. It is the Agency's position that data submitted by companies in support of registration (e.g., toxicity data, feeding studies, environmental chemistry data, etc.) may be compensable, and are not trade secrets. It is our view that upon a showing that the information has been maintained in confidence and that its public disclosure would likely cause substantial harm to the data submitter's competitive position, the confidential formula, financial information and data in support of an application not yet approved, should be accorded confidential treatment.

Ten cases involving data compensation/trade secret disputes are currently at issue in the courts. Pending any final decision on these trade secret issues, we have been enjoined from considering any of the data in question in support of other registrants' applications or have entered into stipulations to that effect. This is a significant problem, as it potentially can affect approximately 12,000 products on which no registration or reregistration actions may be taken until the courts make a final ruling. In the meantime the current registrations continue on the market and applications for new registrations cannot rely on that data without the consent of the owner.

An even more crucial trade secret problem concerns use of confidential formulas. The relevance of data in support of an application is generally determined by comparing one registrant's product with another. Product B cannot rely on Product A's data

unless the two products are the same. Some segments of industry claim that EPA cannot compare any application to a previously registered product without considering the formula of the two products in question, and thus all data are protected under Section 10. Litigation is also pending on this issue, which will have a major impact on the whole reregistration process.

Agency Commitment. EPA is taking several steps to help resolve data compensation complexities:

o a Federal Register notice was issued on October 18 relating to the determination of data compensation claims. In that notice, the Administrator authorizes the Chief Administrative Law Judge to hold hearings and issue Initial Decisions as to claims under Section 3(c)(1)(D).

o the proposed Section 3(c)(1)(D) regulations have been written and were transmitted to the USDA and the Agriculture Committees of Congress in November 1976. They were presented to the Scientific Advisory Panel when it convened in early December.

o a solution to the identicality question in some cases is the submission of complete chemical analyses on the two products showing practical identicality, thus demonstrating the relevancy of prior data to the current action without use of trade secret materials. Some applicants have requested that we accept these reports as evidence of identicality. Where such comparative analyses are not adequate to show relevance of prior testing, the problem remains.

o a paper is being prepared for the House Agriculture Committee which addresses the competitive aspects of FIFRA implementation, including the data compensation and trade secret issues. During the next oversight hearings early next year, we will discuss with the Committee the possibility of amending the Act to clearly define what information falls under the trade secret provisions of Section 10, and how the Agency can use this information during the registration and reregistration process.

E. TRANSITION IMPACTS

1. Background. Many of the problems now being faced by the Office of Pesticide Programs are attributable to the dynamics of changing from the 1947 statute to the new Section 3 regulations under the 1972 amendments. It has been obvious from the beginning that a certain amount of confusion and inconvenience would be experienced in this transition period; however, when it was anticipated that the transition would be but a year or two, the associated problems appeared to be tolerable. Now -- because of the data validity question -- the transition period will be considerably lengthened, and it is imperative that additional thought be given to the transition impacts, especially as they affect applications for new registration.

2. Transition Impacts: PROBLEMS

a) Registration

PROBLEM: How will the Agency treat registrations and conditional registrations now that all chemicals are back in Category V for purposes of data validation?

Discussion: It has been the Agency position that data requirements for registration and reregistration should be separate, and that applications for new registrations should for the most part fully comply with all the requirements of the Section 3 regulations prior to registration. On February 17, 1976, the Agency published in the Federal Register a description of the reregistration process, and placed all pesticides in five categories according to data status: I) compounds for which all supporting data were present, II) compounds for which long-term data were missing, III) compounds for which short-term data were missing, IV) compounds in the RPAR category, and V) compounds unreviewed. Data policy was further described in the May 1976 statement on conditional registration which allowed registrations of products identical or substantially similar to those already registered while long term data gaps were being filled so long as the parent compounds were placed in Categories I or II. With the data validity problem, however, all products are back in Category V (unreviewed) and thus the May statement is virtually inoperative.

The Agency must therefore come to grips with the question of processing new applications while the data validation efforts are underway. It is clear that all new chemicals must meet the new Section 3 requirements fully prior to registration. If the Agency were to insist that every data requirement of Section 3 be met

and validated prior to any new registration of old chemicals, however, (given the fact that data validation will take many years), we could virtually bring new registrations of old chemicals to a standstill. (The Administrator's Pesticide Policy Advisory Committee has passed the following resolution: "Old chemicals now registered will be treated alike regardless of whether they are now registered or will be conditionally registered in the future, while data are being gathered; the definition of old chemicals to include existing products with new formulations.") On the other hand, if we permit any registration of any old chemical without data validation, we would not be protecting the public health. Clearly, to best serve the public interest (which demands a balancing of pest control needs with potential adverse effects impacts), we must take a position intermediate to either extreme.

Several important factors must be noted in this regard:

- the Section 3 regulations require some chronic data which take years to accumulate; thus, while the regulations became effective overnight, the ability of registrants to comply with new data requirements did not;

- during a transition period, it is more logical and less economically and socially disruptive to get from point x to point y gradually rather than abrubtly -- the important thing is to get to point y, and to get there without creating havoc along the way;

- the absence of data does not preclude our ability to make an "unreasonable adverse effects" decision -- if, for example, the Agency has 95% of the studies on a certain pesticide but one long term study is missing, that final study will serve to only incrementally add to our knowledge about the product and our confidence that the product will not pose an unreasonable adverse effect. But that one increment may not prevent the Agency from making a Section 3 finding based on all the information which is available;

- any new uses of old chemicals during the transition period must be supported by validated data pertaining to the new use;

- our primary mandate is to protect public health and the environment; however, we should strive to assure that our registration policies do not disrupt pest control producers and particularly users without achieving environmental protection.

Agency Commitment. The Agency will develop a new registration policy which treats like chemicals in a like manner during the transition period. We plan basically to remove the distinction between registration and reregistration as far as data requirements are concerned. Any application involving a change in use pattern will be treated as a new chemical with respect to the new use, i.e., the full complement of data necessary to judge the environmental impact will be required prior to registration.

A policy statement implementing the new approach to registration and its implications for tolerance setting is being prepared, and will appear in the Federal Register in February 1977. A general description of the process is in Attachment II. Additionally, the Agency plans to exercise an open-minded policy with regard to Section 18 requests for use of new chemicals during the transition period in cases where there is an urgent need for pest control and most of the information needed for registration is developed and looks promising.

b) Status of Guidance Packages

PROBLEM: What is happening to the 72 Guidance Packages previously issued by the Agency?

Discussion. After the need to better review data on hand was discovered, a moratorium was declared on registration. At that time, 72 Specific Guidance Packages covering 2,527 pesticide products had been mailed. The following actions have since been taken with regard to these 72 packages:

-- an acute hazard profile has been built for the Chemical Review File. Most of the earlier packages were built from abbreviated chemical worksheets which are now considered inadequate;

-- external reviews have been added to a substantial number of CRF's;

-- a summary of chemical use history is being added;

-- documentation of the original classification decision has been added to each package.

Agency Commitment. The following actions require completion for the CRF covering the 72 Specific Guidance Packages:

-- use pattern summaries;

-- environmental chemistry summary;

-- literature search;

-- completion of the use history summaries;

-- annotations of data bibliographies with abstracts of prior reviews.

Following the completion of the CRF's for the 72 packages these files will be reviewed for:

-- validation of the data

-- RPAR criteria

Recommendations for action will then be prepared and the CRF's will be submitted to the internal review panel.

Depending upon the changes indicated (if any), either a revision letter or a new package will be issued for each of the Guidance Packages.

c) Labeling

PROBLEM: What actions to improve the pesticide label will be taken during reregistration?

Discussion. While existing pesticide labels are undergoing considerable upgrading as a result of regulatory changes during the reregistration process, these improvements are largely confined to the warning and precautionary statements concerned with the safety aspects of the label. The label format has been standardized to make labels more uniform and easier to read.

Because of time and resource constraints, very little has been done to improve the use directions portion of the pesticide label. A number of problems exist with use directions:

- o inconsistency between directions for the same use on different product name labels of identical formulation;
- o lack of a standard format and nomenclature for presenting a given use direction to insure uniformity and inclusion of all the necessary elements such as method of application, site, timing, etc;
- o a high degree of specificity with regard to pests, which in some cases is considered too rigid;
- o extensive technical language which is too sophisticated for certain user audiences;

- o antidote statements which need to be reviewed and improved.

These problems complicate the following broader issues dealing with the Act, and/or Agency policy:

- o current strict interpretation of 12(a)(2)(g), which according to many user groups gives rise to unnecessary problems of misuse;
- o possible inadequacy of PEPS to meet long-term interpretations and/or specific cases on a broad policy basis;
- o transition from old labels to reregistered labels;
- o coordination of certified applicator training program with label classification changes.

Agency Commitment. To resolve these issues, we will:

1. Initiate improvement of use directions in the reregistration process as follows:

   A. develop a format for the elements found in use directions and the order in which they should appear.

   B. develop an internal training program to alert EPA reviewers to inconsistencies in labeling so that such problems can be addressed in future Guidance Packages.

2. Ask a special Chemical Specialities Manufacturers Association (CSMA) committee to help us develop a new class of labels for home products. A proposal from CSMA is expected within the next few months. Such labels would bear simplified, less technical use directions and general pest descriptions. The Agency could then consider whether or not home labels may serve as a prototype for similar approaches for agricultural labels.

3. Adopt the transitional scheme included as Attachment III for conversion of old labels to reregistered labels.

(d) Use Inconsistent With the Label

PROBLEM: Are all deviations from the label directions illegal?

Discussion: Part of the labeling problem is the issue of "use inconsistent with the label" as incorporated in Section 12(a)(2)(G) of the Act. The Agency has interpreted 12(a)(2)(G) in a "strict" manner, i.e., it is Agency position that any deviation from the label is at least technically a violation of the law. In a series of Pesticide Enforcement Policy Statements (PEPS), the Agency has exercised its prosecutorial discretion by defining those kinds of label deviations against which enforcement action will not be taken.

The PEPS are meant to be an intermediary tool during the transition period between the 1947 Act and the fully implemented 1972 amendments. As the transition period is extended, so is the question of PEPS viability.

Agency Commitment. To help alleviate this problem, registrants will be encouraged rather than discouraged to broaden label directions during registration and reregistration, e.g., the phrase "... and similar corn root pests" and "similar broadleaf weeds in the home lawn." This policy has been used in the herbicide area, and should be expanded to other areas where applicable. The basic difficulty to this approach is the reluctance of some registrants to broaden labels because of potential liability problems.

A more fundamental approach to the problem would be to develop a more flexible interpretation of "use inconsistent with the label." The Report of the House Agriculture Committee issued after the 1975 oversight hearings specified that not all deviations from the label should be considered a misuse, although the Report did not provide any definitive guidance in this regard. During the first half of the year, the Agency will give priority to reviewing the various views on use inconsistent with the label. PEPS were designed primarily with a relabeling completed in 10/76 or 10/77. If the process is to run on longer -- we now expect to 1979-80 -- then other longer term alternatives must be considered including a process of before-use definition of what our reviewers have in mind when looking at label directions, and giving advisory guidance to growers before the use as to whether we consider it inconsistent or not.

It is likely that further Congressional direction will be forthcoming this Spring in the absence of a finite solution before that time.

e) Rebuttable Presumption Against Registration (RPAR)

Background

One of the most significant processes of registration/reregistration, which is particularly intensive during the transition period, is the screening of already registered products to determine if they meet the "unreasonable adverse effects" standard of amended FIFRA. Products which meet or exceed the risk criteria enumerated in the Section 3 regulations undergo an intense risk/benefit analysis under the auspices of the Office of Special Pesticides Review. If any of the risk criteria have been triggered, the Agency may "presume" that the product will pose unreasonable adverse effects on man or the environment. The registrant can rebut that presumption by demonstrating that the risk is not present or that the risk, while valid, can be mitigated so as to reduce actual hazard. Failing to establish that the risk is invalid or can be acceptably mitigated, the registrant also has the option of demonstrating that the benefits exceed the risks of the product's use.

A notice of rebuttable presumption is not tantamount to a notice of intent to cancel. It is rather a statement of the reasons why the Agency presumes against registration, and an invitation for the industry, other Government agencies, users, environmental groups, and the public to provide benefit and risk data. The process may last up to 180 days, during which time the pesticide in question may continue to be sold.

Basically, RPAR is a five-step process:

1. Preliminary review of EPA data files and the relevant literature to determine candidates;

2. Validation of the data to establish the trigger of the unreasonable adverse effects criteria;

3. Notification of the registrant and the public of the RPAR, via the Federal Register and solicitation of input;

4. Submission of rebuttal and/or supporting information by the registrant and interested parties regarding risks and and benefits; and

5. Determination as to whether to register or deny registration, or to initiate cancellation. If the decision is to proceed with a notice of intent to cancel, the Agency must submit the proposed notice to USDA and the Scientific Advisory Panel as mandated by the 1975 FIFRA amendments. If the decision is to proceed with reregistration, the public is notified of the decision and the reasons therefore in the Federal Register.

Seven RPAR's have been issued: Kepone, Chloroform, Chlorobenzilate, Endrin, BHC, 1080 and strychnine. Two chemicals (picloram and sperm whale oil) have been cleared and referred to the reregistration process.

RPAR Problem #1: What is an RPAR candidate & what is its status?

Discussion. RPAR candidates are those compounds which "appear" to meet or exceed the "unreasonable adverse effects" criteria enumerated in Section 3 regulations. They remain candidates until we examine the data which we feel may trigger the criteria. If that examination confirms that the data are good and do meet or exceed the criteria, an RPAR is issued. If, on the other hand, we find that the data are not good or do not meet the criteria, the product is returned to the registration process.

Candidates were identified from three primary sources:

1. the Mrak report ("Report of the [HEW's] Secretary's Commission on Pesticides and Their Relationship to Environmental Health", 1969);
2. "Bioassy of Pesticides & Industrial Chemicals for Tumorigenicity in Mice: A Preliminary Note" done in 1969 for the National Cancer Institute.
3. Referrals from chemical screening by the Registration and Criteria and Evaulation Division in preparation for reregistration.

Registrants have inquired as to the status of their products which are on the candidate list as far as registration and reregistration purposes are concerned.

Agency Commitment. The following policy applies to candidates on the RPAR list:

-- no RPAR candidate will be reregistered until it receives clearance from the Office of Special Pesticide Review.

-- no new registrations involving an ingredient on the RPAR candidate list will be issued unless the registrant can demonstrate that there would be a positive environmental or health benefit from the new registration.

RPAR PROBLEM # 2: Are too many candidates being identified through the acute triggers?

Discussion. The Section 3 regulations at §162.11(a)(3) set out three acute toxicity criteria which if met or exceeded, trigger the RPAR procedure. However, it has been discovered that the criteria are not serving their intended function as a screening mechanism to select out those pesticides which should be subjected to an intensive review. For example, one-third of the insecticides have triggered at least one of the criteria.

Agency commitment. We are presently preparing a proposed regulation change to modify the acute trigger criteria, which we plan to present to USDA and the Scientific Advisory Panel in early 1977.

RPAR PROBLEM #3: How will benefits data be collected and incorporated into the procedures?

Discussion. One important concern to the user community is that EPA receive proper information regarding benefits of a pesticide during the RPAR process. One of the primary purposes of the RPAR review is, in fact, the consideration of benefits data outside the adjudicatory process.

The Agency has been working with USDA to develop a system which will facilitate the collection of benefits data from the field. USDA recently announced the establishment of a national pesticide assessment program to provide input to pesticide decision making. This effort includes participation by seven USDA agencies, land grant colleges, and agricultural components of state governments

and other concerned organizations. Questionnaires will be sent to participators requesting information on the benefits and risk of RPAR candidates. The flow of information should also be augmented by a data use system, which USDA predicts will be operational by July 1977, and will be accessible through existing computer networks. This system will advise participators of the current registration status of pesticide products.

Agency Commitment. EPA has just completed a formal memorandum of understanding with USDA. The memorandum outlines the specific procedures for:

.exchanging existing benefits information,
.gathering new information where appropriate including that for minor uses,
.introducing this information into the RPAR process.

A copy of the memorandum of understanding is Attachment IV.

RPAR PROBLEM #4: Why is the process behind the original schedule and what does this mean in terms of the October 1977 date?

Discussion. According to the original schedule, 21 compounds were to have been reviewed by October to determine whether or not RPAR's should be issued. Unfortunately, the establishment and staffing of the Office of Special Pesticide Reviews took longer than anticipated. The Agency also found that the validation review was more complex than originally thought and that grouping of compounds on the list by major use patterns, e.g., fumigants, wood treatments, cotton insecticides, would provide for more efficient and logical decision making.

Agency Commitment. EPA has just published a new OSPR schedule. Decisions on whether or not to issue RPAR's on that list will be made by October 1977. A copy of the schedule is Attachment V.

f) Petroleum Distillates

PROBLEM: What will the Agency do in the reregistration of pesticides containing petroleum distillates given potential of risk from PNA's?

Discussion. Petroleum distillates are contained in thousands of pesticide products both as inert and active ingredients. Polynuclear aromatic hydrocarbons (PNA) can be found in petroleum distillates. Since some PNA's are carcinogens, the Agency is concerned about the PNA content in pesticide products, and the associated potential hazard.

On September 21, EPA published a proposed method for detecting PNA's through ultraviolet (UV) absorption. Each applicant for registration and reregistration of any product containing a petroleum distillate would be required to provide the Agency with information regarding the PNA content of the distillate as indicated by the UV absorption method. Registrants would also be required to keep records of the UV absorbance of subsequent batches, which shall be made available to EPA upon request. Public input to the proposed action was solicited in the Register notice.

The Agency is evaluating: (1) the risks which petroleum distillates may pose for man and the environment, (2) the type and amount of exposure to petroleum distillates which the public experiences as a result of pesticide products, and (3) the benefits accruing from use of petroleum distillates in pesticides.

Agency Commitment. Because more than 20,000 products are affected by the petroleum distillate question, it would unduly interfere with the production of food and fiber to deny registrations while the risk is being assessed. Therefore, the Agency is preparing a notice to appear in the Federal Register which in effect rebuts the presumption against registration for cetain products and outlines the data requirements which will be attached to conditional registrations.

The petroleum distillate question is but an example of an environmental problem which includes pesticides only marginally (less than 1% of petroleum distillates manufactured are used in pesticides). In all such cases, the Agency should have an overall policy to resolve the entire problem. This dilemma will be further explored as the Agency implements the new Toxic Substances legislation.

Petroleum distillates are also but an example of the general issue of inerts-contaminants (e.g., HCB, dioxin, nitrosamine) which fundamentally affects the registration/reregistration process. The Agency's general approach in this area will be consistent with the PNA situation, i.e., we will attempt to limit exposure while taking appropriate steps to assess the risk.

g) Minor Uses

PROBLEM: How can the Federal Government assist in the registration of needed products which are too minor to justify industry expense?

Discussion: The availability of pesticides for so-called "minor uses" has long been a topic of concern to growers. In general, a pesticide use is considered minor if its market potential is insufficient to economically justify the development of needed data required for registration by the manufacturer. Apart from data development, industry is also concerned about high liability risk in cases where damage may be great even though pesticide use is small.

Before 1972, FIFRA did not require all uses to be Federally registered and did not include penalties if label directions were not followed. Section 12(a)(2)(G) of the amended Act now makes it unlawful "to use any registered pesticide in a manner inconsistent with its labeling." Under the earlier Act, too, intrastate products were not regulated by the FIFRA, and many minor use needs were registered by States. The problem is, then, that it is now a violation of the law to approve minor uses via many of the former techniques and the industry cannot justify the expense of gathering necessary data to achieve Federal registration. It is also anticipated that registrants will drop some minor uses during the reregistration process rather than meet new data requirements. While Section 24(c) of the Act permits the States to register products for special local needs, which include minor uses, such registrations cannot be granted unless a tolerance for the food crop in question already exists. 24(c) thus is not a complete solution.

A cooperative effort to facilitate Federal registration of minor uses has been underway for several years through the Interregional Research Project group (IR-4) at Rutgers, sponsored by USDA and EPA. Just a few years ago thousands of minor use pesticide products needed to be registered. IR-4 liaisons at the various State Agricultural Experiment Stations analyzed and prioritized these needs, and now the current list for agricultural uses, which constitutes the major part of minor use requirements, includes about 700 requests.

Agency Commitment. As a regulatory agency, EPA does not have lead responsibility in obtaining the data needed to support registration; because of the difficulties in the minor use area, however, we will facilitate the resolution of the problems as best we are able. Toward this end, we will take several steps:

1. The Registration Division of OPP is assigning a special manager to "shepherd" minor uses exclusively and to address industry and user group concerns. The possibility of grower organizations becoming registrants will be explored. Instructional material to guide EPA reviewers will also be made available to industry and other interested parties outlining how minor use registrations will be handled.

2. A full time professional from the Registration Division has been assigned to work in IR-4 for the next year to assist in developing complete submissions to the Agency.

3. The 700 requests referred to above will, with the assistance of EPA Regions and the States, be prioritized by the end of January 1977. The prioritized list will be sent to industry representatives to determine their willingness to cooperate in registering/reregistering the proposed uses. Attempts will then be made to identify adequate

substitutes that will not be encumbered by minor use considerations. These combined efforts will permit USDA, EPA, IR-4 and the industry to focus their efforts in dealing with minor uses that are of priority importance.

4. A similar prioritized list will also be developed in January in cooperation with user groups for non-agricultural applications. Since tolerances are not involved, the difficulties in registering these uses are considerably less, although the liability issue remains.

5. EPA is working with USDA to accelerate the cataloging and release of registration use data. The data on registered uses via microfiche is the current mechanism used to convey this use information to the States and to user groups. The use computer system described on page 28 could assist in collecting efficacy and phytotoxicity data from the States. This combined system could well ease the minor use and 24(c) problem by ensuring that users have easy access to needed data on currently registered uses.

6. EPA will encourage Directors of State Experiment Stations to apply for and employ broad, one-year experimental use permits for uses related to those cited on the EPA, IR-4, USDA priority list.

7. Beginning in January 1977, EPA will begin providing brief quarterly progress reports in the minor use area for Congress and other interested parties.

8. EPA will discuss with the House Agriculture Committee the possibility of creating a liability fund for minor use pesticides and exploring such options as user group/non-EPA Federal Agency registration during the next oversight session in early 1977. This might be a means of relieving industry's concern about liability from expanding current labels.

h) Intrastate Pesticides.

PROBLEM: How will EPA register the products currently being marketed solely within a State without a Federal registration?

Discussion. On September 17, 1975, the Agency published a notice in the Federal Register advising all manufacturers of intrastate pesticides of the impending promulgation of new final regulations for the registration and classification of pesticides. To provide for an orderly transition from State to Federal regulation. The Agency has permitted a manufacturers of valid State registrations to continue marketing intrastate so long as they submitted a notice (within 60 days of the effective date of the Section 3 regulations) of this intent to apply for Federal registration. We would notify such registrants, at a later date, when to submit a full application for registration.

Agency Commitment. EPA will issue a Federal Register notice in April 1977 requesting manufacturers of intrastate products to submit an application for Federal registration.

F. Tolerances

Background. Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires that a tolerance (allowable residue level) or tolerance exemption be established for a pesticide that is added to a raw agricultural commodity. A petitioner for such a tolerance must submit to the Agency data on the pesticide's toxicology, residue, and analysis. Toxicological data are also required by the Agency in evaluating whether a pesticide meets the standards for registration as set out in Section 3 of the FIFRA. Hazard evaluation performed to meet the standards of the FFDCA cannot be inconsistent with hazard evaluation performed to meet the standards of FIFRA. Thus, requirements for toxicological tests for pesticides which may result in residues in food or feed, as articulated in the Section 3 regulations and the Registration Guidelines, are equally applicable to registration and tolerance setting activities. Similarly, the data validation program which is aimed at reviewing the validity of data for purposes of reregistration will also pass comment on the validity of data for purposes of tolerance setting. The net result is that the enactment of the '72 FIFRA and the promulgation of Section 3 regulations have blurred the sharp distinctions between regulation and tolerance matters. FIFRA and FFDCA are intrinsically related and the Agency must act accordingly.

Although it would be most desirable to review tolerances for a chemical at the same time that its Chemical Review File is being prepared, two factors argue against doing so: lack of resources to perform both reviews simultaneously and the existence of uncertainties surrounding the tolerance question. Rather than beginning a tolerance review without full resolution of these uncertainties, it would be better to delay the review until a comprehensive set of procedures and policies is developed. Thus, we propose first to study the current procedures and if necessary to amend them; and also develop policies on how to handle interim tolerances, zero tolerances, temporary tolerances, and existing uses which result in residues on food or feed but for which no tolerances exist.

Agency Commitment. EPA intends to:

1. Complete a detailed description of present tolerance setting procedures by January 1977.

2. Perform a comprehensive evaluation of the principles underlying tolerance setting. The Environmental Health Advisory Committee of EPA's Science Advisory Board will be asked to undertake this task.

3. Issue new procedural tolerance regulations -- taking into account the Advisory Committee's findings -- by January 1978.

4. Systematically review tolerances chemical-by-chemical after January 1978 independent of the reregistration process.

As part of the reregistration process, however, some steps can be taken to improve the tolerance situation:

1. Labels will be reviewed to identify those uses which can be expected to result in food or feed residues and for which no tolerances exist. We will impose animal feeding or other restrictions on the label where corrective action is found to be appropriate.

2. Toxicology data will be reviewed in-depth as part of the data validation program for reregistration. If long-term data gaps are discovered and if the pesticide does not exceed any RPAR criteria, the pesticide will be conditionally registered for the length of time necessary to perform and report additional testing. During this period, the pesticide tolerances will remain in effect. They will be reviewed again after the missing data are submitted to the Agency.

III. USE REGULATION

A. Background

Congress, in passing the 1972 Act, recognized that pesticide use presented both benefits and risks to human health and the environment. One of the major additions to pesticide legislation was the strengthening of regulatory controls over the uses and users of pesticides.

The new Act accepts the premise that most pesticides, if correctly registered and properly labeled, can be used by the general public with the assurance that human health and the environment would be adequately protected. These are general use pesticides.

The Congress also recognized that there would be certain pesticides and certain uses of pesticides which, because of their potential hazard, should not be used by an applicator who does not have the needed level of skill or awareness. They determined, therefore, that such a use would be classified as a restricted use pesticide. Under the Act, a person applying restricted use pesticides would need to become a certified applicator or would have to use restricted use pesticides under the supervision of a certified applicator, or be subject to any other restriction deemed appropriate by the Administrator.

The Act provides that EPA shall establish standards for certification, and that States shall conduct certification programs. EPA published standards in October 1974 that must be met by private applicators (farmers) and 10 categories of commercial applicators: (1) agricultural pest control; (2) forest pest control; (3) ornamental and turf pest control; (4) seed treatment; (5) aquatic pest control; (6) right-of-way pest control; (7) industrial, institutional, structural and health-related pest control; (8) public health pest control; (9) regulatory pest control; and (10) demonstration and research pest control.

EPA published guidelines for use in developing State Certification Plans in March 1975. After considerable controversy over methods for certifying farmers, an amendment to the FIFRA was passed in 1975 authorizing training as an acceptable certification method. The program is now generally well received and commendable progress is being made.

A major advantage of certification is that it eliminates the "all or nothing" approach to registration and cancellation decisions. Rather than removing a pesticide from the market, or denying its access to the market, the Administrator can restrict the uses of the pesticide and be assured that the product will be used only by skilled applicators. This in turn provides the degree of human health and environmental safety needed to authorize the use of the pesticide.

B. Classification

The key to implementation of the State Certification Plans is the classification of pesticide uses. In the future, all new products will be classified restricted or general during the registration process. The reregistration and classification of the more than 33,000 pesticide products currently registered and on the market is underway.

Classification involves:

.establishing criteria for identification of restricted uses;
.evaluating the toxicity and the exposure from use patterns against these criteria;
.considering the use history in terms of reports of adverse effects involving the product;
.making an initial EPA determination;
.allowing registrants to consider this determination;
.discussing any disagreements; and
.making a final EPA determination.

This process will continually change the number of restricted uses. Uses will be added and removed as the registration and reregistration process moves forward.

Several issues discussed earlier have caused serious delays in registration. Consequently, classification, which is integral to the reregistration/registration process, is about to get underway.

C. Certification

As indicated above, the amended FIFRA, Section 4, calls for a cooperative Federal/State program to provide for the certification of applicators of restricted use pesticides. Through concerted technical and funding assistance from EPA to all States over the past 2 years, major progress has been made toward the goal of fully operational State plans nationwide by the October 21, 1977, deadline established by Congress. To date, 47 States have formally submitted plans to EPA for approval. Nine more States are expected to submit plans during the next several months. Applicator training programs have been established in all States and have achieved a generally high level of acceptance among private and commercial applicators alike.

Over the past two years, and in cooperation with the States and the USDA Extension Service, EPA has developed and published a host of training materials which can be used by the State Cooperative Extension Services which have the major responsibility for training applicators. The basic concept of this cooperative approach is that EPA would sponsor the development of training materials which would be an extension of our standards for certified applicators. These materials would, therefore, of necessity be minimal in terms of all the complex material that might be made available for presentation. The States would then add their more specific requirements to this "core" material. This concept has worked well and has led to reasonable and well developed training programs in almost all States.

It should be pointed out that training is not mandatory under the Act. All States, however, have recognized the value of training, education, and voluntary compliance, and have made training a major component of their certification program.

D. Use Regulation: PROBLEMS

PROBLEM # 1: How can the States certify applicators in the absence of a definitive list of restricted uses?

Discussion. Training and certification of applicators are intended to be directed at the proper and safe use of pesticides classified for restricted use. It can be assumed that for-hire commercial applicators will need to use one or more restricted use pesticides in the course of their normal operations. The same assumption cannot be made with respect to the so-called "non-commercial" and private applicators. The result is that for-hire applicators are participating in training and certification programs, while many non-commercial and private applicators are not, deferring participation until pesticides are classified and a determination can be made as to the necessity of becoming certified. EPA long ago recognized this likelihood, and in 1975 prepared and distributed a list of active ingredients which presumably would have one or more restricted uses. EPA intended that the list would provide information, pending actual product classification, sufficient to enable States to develop and implement programs which would reach maximum numbers of potential users of restricted use pesticides prior to October 21, 1977. However, there is still uncertainty among States and applicators as to the final result of classification, leaving training and certification programs in many States short of the necessary momentum.

Agency Commitment. In conjunction with States, industry, and user groups, EPA has for the past month been developing a more comprehensive listing of active ingredients likely to have one or more restricted uses. The list was completed and distributed in early December. It should provide greater certainty of classification and thereby increase the impetus of State training and certification programs.

It is important to note that a good "rule of thumb" to apply is that an applicator using pesticides with "danger"and skull and crossbones on the current label, labeled for use in aquatic environment or in forests, or registered as fumigants, should plan to be certified since these types of uses are most likely to be restricted.

EPA recognizes the difficulty in frequent changes in the number of uses that are restricted. Such changes create problems for the Extension Service training the applicators, for the State Lead Agency administering the program, and for the farmer who may or may not require certification, depending on which uses are restricted. To compensate for these difficulties, we have taken three steps: 1) ensured that certification of farmers is an uncomplicated administrative process with many options available to the States; 2) authorized an emergency program to allow an uncertified farmer to purchase a restricted use pesticide under circumstances beyond his control, and; 3) established a phasing concept in terms of label changes to reflect the restricted use determinations, and in terms of the date by which the purchaser must either be certified or be the agent of a certified applicator. It is the Agency's intent not to require a label change in the middle of a growing season which could disrupt or inconvenience applicators.

PROBLEM #2: What is the relevance of the October 21, 1977, date to those States whose plans have been approved on a contingency basis?

Discussion. Of the forty-six plans formally submitted to date, all but five have been or will be approved contingent upon passage of legislation and/or promulgation of regulations. Most of the remaining eight States will receive approval of their plans also on a contingency basis. In order to have a fully approved and therefore fully operational plan, a State must satisfy all contingencies; that is, it must enact any necessary legislation and promulgate all necessary regulations. Failure of any State to accomplish these actions by October 21, 1977, will leave such a State deficient in requisite legal authorities, thereby preventing EPA from granting full approval to that State's plan. The effect of this situation, in terms of law, may be the termination of that State's authority to carry out Section 4 of amended FIFRA.

Agency Commitment. EPA will continue to review and provide comments on all proposed legislation and regulations, testify at legislative and public hearings when requested by a State, and take other appropriate actions to ensure that all States have received information and assistance necessary to achieve full approval status.

PROBLEM #3: What will happen in a State without an approved plan by October 1977?

Discussion. Despite the best efforts of this Agency and the States, circumstances may arise in one or more States to prevent compliance with all requirements necessary for full plan approval by the October 21, 1977, implementation deadline for certification. It is EPA's legal opinion that in such a situation EPA has two available options: (1) to defer enforcement against use of restricted use pesticides by uncertified applicators in States without fully approved plans until such time as those States satisfy the requirements of, and are granted full plan approval; or (2) to make certification available through some other mechanism or combination of mechanisms such as:

-- developing a Federal certification program
-- relying on the certification apparatus of a neighboring State.

Agency Commitment. EPA is fully cognizant of the ramifications of these options. Decisions are being made, and policies developed, to structure programs necessary to take action under both. Circumstances will dictate whether one or both options will be exercised, but regardless of the course taken, the actions will be based not only in law, but also in equity. Restricted use pesticides will not be denied to those needing and qualified to use them.

PROBLEM #4: How will Federal employees be certified?

Discussion. In the State Plan Regulations published March 12, 1975, provision was made for the Government Agency Plan (GAP), through which Federal employees could become qualified for certification. The act of certifying Federal employees would be carried out by the individual States. The failure of GAP to generate much interest among Federal agencies, and recent Supreme Court decisions rendering tenuous the concepts underlying GAP, have caused EPA to consider other approaches. The most viable approach is to treat Federal agencies as States for purposes of certification. A Federal agency would thus certify its employees under a plan developed in accordance with the State Plan regulations and approved by EPA. Federal agencies not desiring to develop a plan would have the option to voluntarily submit to State jurisdiction for certification.

Agency Commitment. EPA will prepare amendments to the State Plan regulations to provide for Federal agency certification, and will work with agencies wishing to follow this course in the development of necessary programs and plans. These efforts are underway.

PROBLEM #5: How will applicators on Federal Indian reservations be certified?

Discussion. State jurisdiction on Federal Indian reservations varies widely. The State Plan Regulations take note of this fact and make provision for Indian governing bodies to develop their own certification plans or to enter into cooperative agreements with States for the purposes of carrying out certification under those States' plans. To date few Indian governing bodies have exercised either option or made their desires known. At the same time, little effort has been made by States or the Federal government to inform Indian governing bodies of the requirements of Section 4 and the available courses of action.

Agency Commitment. EPA will increase its efforts in working with the Bureau of Indian Affairs to contact Indian governing bodies and to ensure the development of appropriate certication programs on all Federal Indian reservations.

PROBLEM #6: How will EPA ensure that State certification and training programs are being carried out in accordance with approved plans, and that the purposes of FIFRA are being achieved?

Discussion. The submission and approval of State plans is only the first step in implementing Section 4. The heart of implementation lies in the conduct and quality of State certification and related training programs. To ensure attainment of the goals of certification, a system must be established not only to measure State adherence to the provision of approved plans, but also to evaluate the qualitative effectiveness of certification and training.

Agency Commitment. A guidance document is being developed to provide the basic structure for Regional Office evaluation of State certification and training programs. The evaluation will begin this winter. In addition, a Request for Proposal (RFP) will be issued for a major contract to provide base line data on quality of current pesticide use, and to evaluate the overall impact of certification and training. This second element of the contract will involve not only an evaluation of the relative improvement in the quality of pesticide use, but also an effort to determine the adequacy of various EPA and State certification requirements in achieving the purposes of FIFRA.

PROBLEM #7: Can States be expected to assume the full cost burden of certification and training programs?

Discussion. Prior to the passage of amended FIFRA in 1972, few States had in place or intended to establish comprehensive pesticide use control programs. It can be fairly said that many, if not a majority, of the States would not now be constructing such programs in the absence of the FIFRA requirement that they do so. The reasons are both political and economic. The Federal Government proceeded to urge States to participate on a cost sharing basis for start up costs, presuming that the States would then continue the program on a maintenance basis solely with State funds. The exact point of the termination of Federal assistance is difficult to determine precisely, but it appears that continued assistance at a reduced level is appropriate for FY '78 and perhaps FY '79.

Agency Commitment. EPA has received an appropriation of $4.6 million in FY '77 for certification and training assistance, and will request additional funds in FY '78 and consult with the States on FY '79. The amount of funds to be requested for the latter two fiscal years will be determined on the basis of joint EPA/States assessment of need.

IV. ORGANIZATION

It is clear from the preceding sections that there are two vital but nonetheless separate processes in pesticide regulation: the scientific evaluation and the regulatory decision. Scientific expertise is necessary to validate and interpret data; regulatory judgment is necessary to apply the scientific evaluation to risk/benefit decision making in which social and economic as well as scientific factors must be weighed to reach final conclusions. The scientist must be free to make scientific judgments and the regulator must be able to apply the findings of scientific reviews to the requirements of the law and regulations in drawing conclusions.

The most important tasks within OPP all require scientific support. The reregistration process must look to scientists for data validation and assessment of data gaps. The registration and tolerance setting process for new applications and petitions depends upon scientific evaluation of supporting data. The RPAR process looks first for the scientific validation of the information triggering the Section 3 162.11 criteria. In other words, there are three major program elements responsible for regulatory decisions which rely on scientific data validation and evaluation efforts:

1) registration/tolerances
2) reregistration;
3) OSPR

Presently, primary scientific support is divided up among the Criteria and Evaluation Division, the Registration Division, and the Technical Services Division. Because of the priority need for data validation and review which cuts across Division lines, it is only logical to reassemble the bulk of scientific personnel in a new Division which will be responsible for review of supporting and hazard data. During the recent past, OPP has not had adequate staff in certain critical skill pools to accomplish all of its objectives in a timely fashion, a condition that has been worsened by the fact that the program's human hazard and environmental effects analytical talent is scattered across three Divisions.

For these reasons, OPP management has decided to seriously pursue an organizational regrouping of some critical functions and activities. Principally involved are those scientists with the responsibility for hazard evaluation and hazard data validation, and those scientists involved in the aggregation of use data and the preparation of the benefits cases under RPAR. However, to complete that effort most responsibly, OPP must also look at the other segments of the organization as well and take this particular opportunity to make some necessary changes in location of some additional functions which are supportive of hazard assessment and benefits case preparation.

Accordingly, OPP has taken a first cut at some major changes which appear not only desirable, but essential. Stated somewhat simply, these changes would go generally as follows: The science directorate in the Registration Division, (RD) with one exception, along with the Metabolic Effects, and the Chemistry Branch, and a portion of the Ecological Effects Branch in the Criteria and Evaluation Division would be consolidated in a newly created Hazard Evaluation Division (HED). A portion of the staff in RD's Efficacy and Ecological Effects Branch would also be moved to HED. The Registration Division would retain its Pesticides Registration Office structure largely as is including the Special Registration directorate.

The pesticides use data expertise in the Technical Services Division (TSD) would be combined with similar expertise and functions now existing in the Plant Studies and Ecological Effects Branch in C&E into a use data/efficacy - RPAR benefits program within TSD. Just how that program would be actually organized is still very much an open question. The Economics Analysis Branch would be relocated to TSD, and would retain its Branch status.

The Technical Services Division would retain the Health Effects and Ecological Monitoring programs to which would be added the Pesticides Episodes Reporting System now located in the Operations Division. The laboratories now in TSD would remain in that Division with the addition of the laboratories and analytical reference program now run in the Registration Division. The System Support Branch and portions of the Information Branch would be transferred to a newly created Management Operations Division. That portion of the Information Branch which would remain in TSD are those functions with lead responsibility for use data collection and analysis vis a vis RPAR benefits cases.

The newly created Management Operations Division would have not only the responsibilities just mentioned but also those functions presently vested in the Office of Program Planning, Evaluation and Administration.

The Office of Special Pesticides Review would be given Division Status, but would remain essentially unchanged. The Operations Division would, except for the loss of the Pesticides Episode Reporting Program to TSD, remain as it is now.

Separating the scientific from the regulatory functions in each area will optimize the use of both scientific and management skills. A proposed reorganization chart is Attachment VI; OPP has asked for its employee's thoughts on this proposal, and management in pursuing it with Agency and Civil Service personnel experts.

LIST OF ATTACHMENTS

I Summary of Problems and Commitments

II Summary of New Approach to Registration/Reregistration

III Label Conversion Schedule

IV USDA/EPA Memorandum of Understanding

V Revised RPAR Decision Schedule

ATTACHMENT I

SUMMARY OF PROBLEMS AND COMMITMENTS

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ATTACHMENT II..

12/10/76

DRAFT

Summary of New Approach

to Registration/Reregistation

1. Data requirements for new registrations and reregistrations will be identical. Since the same finding of absence of unreasonable adverse effect must be made in each case, there really is no basis for distinguishing between the two.

2. Pesticides considered for reregistration will require, at time of application, general chemistry data and acute and subacute toxicity data for mammals, fish, and birds. If other required data are not available at time of application, the pesticide may be conditionally reregistered for the length of time necessary to perform the requisite testing if there is no indication that the product may otherwise pose an unreasonable adverse effect.

3. Old Chemical; Old use pattern: New registrations of products identical to currently registered products will be treated in a similar manner. The short term data described in 2 above will be required at time of application. All other required data must be cited by the applicant accompanied by a signed offer to pay statement. However, if any data other than that described in 2 above are not available for citation -- i.e., the tests have not been performed -- then the applicant will be granted a conditional registration allowing him the time necessary to perform the required tests.

4. Old Chemical; New use: New registrations of products which are not identical to currently registered products but which contain currently marketed active ingredients will be treated as follows. If the new pesticide is similar to a currently registered one -- i.e.,

adds a new pest to the label or involves a relatively minor change in formulation -- then in addition to the short term data described in 2 above, data to support the efficacy of the new formulation against the new pest will be required at time of application.

If the new pesticide includes a new food or feed crop on its label, the registration will be granted if the Agency determines that the available data can support the safety of the additional use, and there is enough data to support a tolerance under the FFDCA. Such factors as the percentage of the diet contributed to by the new crop, the percentage of the Allowable Daily Intake already taken up by other food uses of the chemical, and the results of recent Market Basket Surveys will be taken into consideration in making this determination.

Finally, if the new product involves a changed use pattern, its registration will be approved if data are available to evaluate the safety of any additional human or environmental exposure caused by the changed use.

In all cases, if data other than that necessary to make the above determinations are not available at time of application, the applicant will be given a conditional registration for a length of time necessary to perform the missing tests.

5. New Chemicals: Pesticide products with new ingredients or which otherwise do not fall into any of the above categories will require the full range of data at time of application -- no conditional

registrations will be approved.

6. Amendments will be treated according to the principles of 4 above for new registrations. That is, amendments including formulation changes of a minor nature, or additions of new pests or minor uses will be approved conditionally if short-term data and additional safety and efficacy data to support the amendment are available at time of application.

If the amendment involves a major crop or changed use pattern, a scientific and regulatory judgment will be made as to whether the additional risks incurred by the amendment are offset by the benefits for the period of time necessary for the applicant to fill data gaps.

CONVERSION SCHEDULE FROM NON-CLASSIFIED TO CLASSIFIED LABELS

ATTACHMENT III

Classification Decision Sent to Registrant	RD Label Approval to Registrant	Label in Effect for all Production	Label in Effect for all Channels of Trade
Reregistration	(60 days for submission 30 days for approval)		
RESTRICTED USES called in prior to May 21, 1977	3 mo. after call-in	October 21, 1977	December 21, 1977
May 21, 1977 - July 31, 1977 (assume all restricted called-in by 7/21/77)	no later than Oct 21, 1977	December 21, 1977	February 21, 1978
GENERAL USES called in after Jan. 21, 1977	3 mo. after call-in	6 months after receipt	Not Applicable
called in prior to Jan. 21, 1977	3 mo. after call-in, no later than April 21, 1977	October 21, 1977	Not Applicable
New Registrations before October 21, 1977	Upon completion of review	October 21, 1977	October 21, 1977
After October 21, 1977	Upon completion of review	Effective Immediately	Effectively Immediately
Case-by-case extensions may be granted upon submission of written justification to RD (cans, labels molded into plastics, etc.)			

ATTACHMENT IV

MEMORANDUM OF UNDERSTANDING
between
THE U.S. DEPARTMENT OF AGRICULTURE
and
THE U.S. ENVIRONMENTAL PROTECTION AGENCY

I. Purpose

The purpose of this Memorandum of Understanding is to formalize the working relationship between the United States Department of Agriculture (USDA) and the U. S. Environmental Protection Agency (EPA) that provides for improving the capability of both Agencies to conduct pesticide benefit/risk assessments. The Memorandum of Understanding identifies, consistent with existing statutory authority, the principles and policies of cooperation between the two Agencies and describes the general management and operational approaches that will govern the planning, approval, underwriting and conduct of the cooperative effort to accomplish mutually agreed upon objectives. This Memorandum is within the context of the overall Memorandum of Understanding as signed by the Secretary of Agriculture and the Administrator of EPA, July 31, 1974.

II. Background

The USDA is the prime Federal Agency with responsibility for assuring an adequate supply and efficient production of food, fiber, forest and other agriculturally-related products and improving the welfare of rural people. EPA has lead Federal responsibility in regulatory actions to protect the environment. The 1972 amendments to the Federal

Insecticide, Fungicide and Rodenticide Act provided EPA with the responsibility for regulating the use of pesticides. Additionally, the legislative amendments to the Act in 1975 (PL 94-140) provide that EPA must notify the Secretary of Agriculture 60 days prior to publication in the Federal Register of intent to cancel a pesticide product, except in cases where the Administrator of EPA determines that there is an imminent hazard to human health wherein notification is waived. USDA has 30 days to respond. This response is to be published jointly with the EPA notice.

With those pesticides that are presumed to present an unreasonable adverse effect on the environment, an accurate benefit/risk assessment is required to determine whether or not the pesticides should be registered. Such assessments are multi-disciplinary, involving input from biological, physical and social sciences. In this Memorandum, both Agencies recognize the importance of benefit/risk assessment, and the desirability of a viable cooperative working relationship to carry out designated responsibilities.

III. Policy

It is the policy of the two agencies that they work together to develop objective and accurate data and related information required for benefit/risk assessments of pesticide uses and use patterns subject to a presumption to refuse to register or to reregister. It is agreed that this will be done in a manner which recognizes and utilizes the capabilities of each agency to the greatest feasible extent in either making resources available to the other agency or for the joint

planning and execution of activities. Consistent with its broad agricultural responsibilities, USDA and States/universities are recognized as major sources of information on pesticide uses, relative effectiveness of pesticides and the importance of specific pesticide uses for agricultural and forestry purposes. When USDA notifies EPA that it is not able to supply the necessary information for uses such as industrial, home and garden, and agricultural, EPA may work with any available data source. EPA is recognized as a basic source of information on pesticide registration and environmental and health hazards associated with pesticide use. Both agencies have important contributions to provide on environmental aspects of pesticide use.

IV. Organization and Policy Management

USDA will establish an appropriate mechanism to plan, manage, and conduct activities. This mechanism involves a Steering Committee composed of Associate or Deputy Administrators of key Departmental agencies and State/University representatives. This Committee will be chaired by the Coordinator of Environmental Quality Activities, Office of the Secretary.

The Steering Committee will draw upon the technical expertise of key agencies through a Technical Advisory Group. The Technical Advisory Group will be chaired by the USDA Pesticide Coordinator. The Steering Committee will establish Assessment Teams for pesticides or groups of pesticides requiring detailed assessments. The Assessment Teams will develop a plan of work. The individual agencies, through membership on the Steering Committee, will concur in plans of work and mutually approve the commitments required to implement the plans of work.

EPA will interface with the USDA Steering Committee in addressing policy issues, delineating specific joint activities, and to assure that both agencies are fully aware of ongoing efforts in the respective agencies. Additionally, EPA will identify a contact person to interface with the Technical Advisory Group and serve to facilitate information exchanges. When Assessment Teams are in existence, EPA will also identify a person at the technical level to interact with the Assessment Team Leader and to assign EPA members to assure that all information relevant to the data collection and assessment efforts are utilized.

It is understood that, as appropriate, individual sub-agreements to this general agreement will be developed to identify individual activities and resource commitments.

V. General Guidelines and Provisions

It is agreed that:

a. EPA and USDA will share all available data and analyses required for assessment work, but will be free to reach independent interpretations of the information.

b. EPA will channel its requests for agriculture and forestry related information and analyses initially through a central office in USDA to be designated. Information in central data banks will be made available. For other information needs not in central banks, consideration will be given to formation of assessment teams. Upon recommendation of the USDA/University Steering Committee, requests for information will be passed to the States. Each state system will be free to clarify the extent to which information is available and the ability of their system to be responsive to requests from assessment teams or EPA requests for other data. EPA will be advised within 15 days if requested data cannot be made available within the required time frame and/or when available data can be delivered.

c. USDA, States/Universities and EPA will continue joint efforts to determine data requirements and availabilities in order to identify data gaps and facilitate filling those gaps.

d. USDA and States/Universities will develop and provide to EPA new data to the extent possible, given resources available in the program.

e. EPA will share on a continuing basis with USDA its timetable of actions in the RPAR process and the bases for triggering RPARs.

f. EPA will inform USDA of decisions on pesticide uses which in turn may be assessed by the States and USDA.

g. EPA will appoint a contact person to channel information requests and exchange of information through the USDA Pesticide Coordinator as Chairman of the Technical Advisory Group.

h. In cases where an Assessment Team is assembled by USDA, OSPR/OPP, EPA will appoint an EPA technical person(s) to work with each Assessment Team as deemed appropriate.

i. EPA will advise USDA of its intentions to secure needed data or information in cases where an assessment team is not established by USDA.

Both agencies agree that:

1. Pesticide benefit/risk assessment is multi-disciplinary, in which inputs from biological, physical and social sciences are desirable;

2. Accurate, objective benefit/risk assessments are desirable for implementing certain provisions of FIFRA as amended;

3. The information flowing from the cooperative effort is subject to independent agency assessment;

4. This Memorandum does not inhibit in any way the participation of either agency in any hearing, litigation process or regulatory action initiated under FIFRA as amended, or other State or Federal statutes;

5. This Memorandum does not prohibit either Agency from obtaining additional data that will be available to both parties;

6. This Memorandum does not alter or negate any existing agreements, except as both agencies agree; and,

7. Working documents and/or clarifying statements regarding operational relationships will be developed, as appropriate, to facilitate the cooperation agreed to in this Memorandum.

VI. Funding

The specific details of the levels of support to be furnished one agency by another with respect to funding will be developed in specific sub-agreements.

VII. Procurement Policies

Any program or project activities undertaken by USDA for EPA or vice versa may involve contractual arrangements with non-governmental institutions. When such arrangements are necessary, they will be conducted in a manner consistent with policy, regulations and procedures of the contracting agency.

VIII. Public Information and Coordination

Timely release of information to the public regarding activities implemented under this Memorandum will be an objective of both agencies.

IX. Amendment and Termination

A. This Memorandum may be modified or amended by written agreement between USDA and EPA.

B. This Memorandum may be terminated by mutual agreement between USDA and EPA.

X. Effective Date

This Memorandum is in effect when signed by both agencies.

USDA

Deputy Assistant Secretary for
Conservation, Research and Education

November 26, 1976
Date

EPA

Assistant Administrator for
Water and Hazardous Materials

December 2, 1976
Date

ATTACHMENT V

REVISED RPAR DECISION SCHEDULE

Reproduced from best available copy.

December 8, 1976

MAJOR USE CATEGORY AND CHEMICAL OR CHEMICAL CLASS	PLANNED RPAR DECISION DATE
INSECTICIDES - CANINE Lead Acetate	January 1, 1977
LINDANE	January 15, 1977
HERBICIDES - FOOD Diallate Triallate Pronamide	February 15, 1977
RODENTICIDES Arsenic Trioxide	March 15, 1977
INSECTICIDES - COTTON Toxaphene EPN	March 15, 1977
WOOD PRESERVATIVES Arsenic Pentoxide Sodium Arsenate Ammonium Arsenite Sodium Pyroarsenate Pentachlorophenol and salts Creosote and related compounds	March 15, 1977
HERBICIDES - COTTON DESSICANTS Arsenic Acid Paraquat DEF Merphos	March 15, 1977
FUNGICIDES - FOOD EBDC Benomyl	March 15, 1977
DISINFECTANTS - DEODORANTS Safrole	March 15, 1977

GRAIN FUMIGANTS — April 1, 1977

- Ethylene Dibromide
- Ethylene Oxide
- Carbon Tetrachloride

HERBICIDES - WEED CONTROL — April 15, 1977

- Monuron
- Cacodylic Acid and its sodium salt
- Disodium Methanearsenate (DSMA)
- Monosodium Methanearsenate (MSMA)
- Calcium Acid Methanearsonate
- Monoammonium Methanearsonate (MAMA)
- Amine Methanearsonate (AMA)
- 2,4,5-T and related compounds

FUNGICIDES - NONFOOD — April 15, 1977

- Cadmium
- 2,4,5-Trichlorophenols
- 10,10'-Oxybisphenoxarsine

SOIL FUMIGANTS — April 15, 1977

- DBCP
- PCNB

INSECTICIDES - FOOD — May 1, 1977

- Dimethoate
- Carbaryl
- Trichlorfon
- Perthane
- Rotenone
- Calcium Arsenate
- Copper Arsenate
- Lead Arsenate (Standard)
- Lead Arsenate (Basic)

INSECTICIDES - NONFOOD — May 1, 1977

- Paris Green
- Sodium Arsenite
- Phenarsazine Chloride

INSECTICIDES - HOUSEHOLD — June 1, 1977

- DDVP
- Piperonyl Butoxide

RPAR'S ISSUED

CHEMICAL	DATE
Kepone	3/19/76
Chloroform	3/24/76
Chlorobenzilate	5/14/76
Endrin	7/19/76
BHC	10/12/76
Strychnine	11/22/76
Strychnine Sulfate	11/22/76
1080	11/22/76
1081	11/22/76

CHEMICALS RETURNED TO REGISTRATION DIVISION

CHEMICAL	DATE
Picloram	3/21/76
Sperm Oil	11/15/76

VOLUNTARY CANCELLATION - SECTION 6(a)(1)

CHEMICAL	DATE
OMPA	5/20/76
Strobane	6/18/76
Aramite	Pending
Chloranil	Pending
Copper Arsenite	Pending